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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Jose Flores, Plaintiff, v. GlaxoSmithKline, LLC; Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim USA Corporation; Pfizer, Inc.; Sanofi US Services Inc.; Sanofi-Aventis U.S. LLC; Safeway, Inc.; Safeway Health, Inc; and DOES 1 through 100, inclusive, Defendants.	Case No. 3:20-cv-03959 **NOTICE OF REMOVAL OF ACTION** **DEMAND FOR JURY TRIAL**

DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM USA CORPORATION, GLAXOSMITHKLINE, LLC, PFIZER, INC., SANOFI US SERVICES INC., AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim USA Corporation, GlaxoSmithKline, LLC, Pfizer, Inc., Sanofi US Services Inc., and Sanofi-Aventis U.S. LLC (collectively, "Removing Defendants") hereby give notice of removal of this action, *Jose Flores v. GlaxoSmithKline, LLC et al.*, Case No. RG20061576, from the Superior Court of the State of California in and for Alameda County to the United States District Court for the Northern District of California.

INTRODUCTION

1. This action is one of hundreds of related lawsuits filed against manufacturers and sellers of Zantac (ranitidine), an antacid medication, alleging that the medication causes various cancers. On February 6, 2020, the Judicial Panel on Multidistrict Litigation ("JPML") created a Multidistrict Litigation ("MDL") in the Southern District of Florida before Judge Robin Rosenberg for pretrial coordination of cases like this one "in which plaintiffs allege that they developed cancer as a result of NDMA formed from Zantac." *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 2020 WL 582134, at *2 (J.P.M.L. 2020). To date, over 300 actions have been transferred to the Zantac MDL.

2. On May 11, 2020, Plaintiff filed this Complaint in the Superior Court of the State of California in and for Alameda County against the Removing Defendants, which had manufactured or sold Zantac over various time periods. The thrust of this Complaint—like those already pending in the MDL—is that Plaintiff ingested over-the-counter ("OTC") "Ranitidine-Containing Drugs," and as a result, developed cancer, in this case kidney cancer. Compl. ¶¶ 10-11. The Removing Defendants are not citizens of California for diversity purposes. *See id.* ¶¶ 25, 27, 29, 32-33, 35. A copy of the Complaint is attached as **Exhibit A**.

3. Unlike the cases in the MDL—including cases filed by these same plaintiffs' lawyers—this Complaint also names California-based retailers as Defendants in an effort to destroy diversity jurisdiction. Specifically, the Complaint includes Safeway, Inc. and Safeway Health, Inc. (collectively, the "Retailer Defendants") as named defendants. *Id.* ¶¶ 37-38. The Retailer Defendants are alleged to be citizens of California for diversity purposes. *Id*.

4. As further explained below, the Retailer Defendants are fraudulently joined in this action because—on its face—Plaintiff's complaint fails to allege any viable cause of action against them, and therefore their citizenship must be ignored for purposes of diversity jurisdiction.

5. ***First***, Plaintiff cannot state any viable strict products liability claim against the Retailer Defendants because those claims are preempted by federal law. The Retailer Defendants lack the legal authority under U.S. Food and Drug Administration ("FDA") regulations to unilaterally alter Zantac's government-approved labeling or to manufacture the product differently. *See, e.g.*, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) ("If the Manufacturers had independently

changed their labels to satisfy their state-law duty [to attach a safer label], they would have violated federal law."); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012) ("As a distributor of Fosamax, Watson has no power to change Fosamax labeling. That power lies with the applicant who filed the New Drug Application . . . seeking approval to market Fosamax.").

6. ***Second***, Plaintiff does not state a viable negligence claim against the Retailer Defendants. The basis for Plaintiff's claim is that the Retailer Defendants allegedly failed to ascertain that the products at issue can degrade under certain conditions to form a compound called N-nitrosodiethylamine ("NDMA") and failed to properly store Zantac to avoid such degradation. Compl. ¶¶ 289, 291. It is black-letter law that retailers do not have a duty to inspect or test products in common use for defects unknown to them. *See Sears, Roebuck & Co. v. Marhenke*, 121 F.2d 598, 600 (9th Cir. 1941) (applying California law) (a retailer "who purchases and sells an article in common and general use, in the usual course of trade, without knowledge of its dangerous qualities is not under duty to exercise ordinary care to discover whether it is dangerous or not"); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1485–86 (1999) ("[I]mposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the ***unknown outcome of testing that was not done***, would be beyond the pale of any California tort doctrine we can identify.") (emphasis in original). Otherwise, every retailer in California would have the responsibility to conduct a battery of scientific testing on all pharmaceuticals stocked on its shelves, despite their FDA approval, in order to independently ascertain their safety. That is not the law.

7. Because the Retailer Defendants are fraudulently joined, federal jurisdiction over this action is proper based on complete diversity between Plaintiff and all properly joined defendants.

JURISDICTION

8. The Removing Defendants remove this action on the basis of diversity jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 and the doctrine of fraudulent joinder.

9. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because: (1) there is complete diversity between Plaintiff and the properly joined Defendants; (2) the amount

in controversy exceeds $75,000, exclusive of interest and costs; and (3) all other requirements for removal have been satisfied.

BASIS FOR REMOVAL

I. There Is Complete Diversity Between Plaintiff and the Properly Joined Parties.

10. Plaintiff is a citizen of California. *Id.* ¶ 9.

11. The properly joined defendants are all citizens of states other than California. *See id.* ¶¶ 25, 27, 29, 32-33, 35.[1]

12. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Ridgefield, Connecticut. *Id.* ¶ 25. Boehringer Ingelheim Pharmaceuticals, Inc. is, therefore, a citizen of Delaware and Connecticut.

13. Defendant Boehringer Ingelheim USA Corporation is a corporation organized under the laws of Delaware with its principal place of business in Ridgefield, Connecticut. *Id.* ¶ 27. Boehringer Ingelheim USA Corporation is, therefore, a citizen of Delaware and Connecticut.

14. Defendant GlaxoSmithKline LLC is a limited liability company organized under the laws of Delaware with its principal place of business in Wilmington, Delaware. Its sole member is GlaxoSmithKline Holdings (America) Inc., a corporation organized under the laws of Delaware with its principal place of business in Wilmington, Delaware. *See* Attachment to Corp. Disclosure Statement, *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, Dkt. 43-1. GlaxoSmithKline LLC is, therefore, a citizen of Delaware.

15. Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New York, New York. *Id.* ¶ 32. Pfizer Inc. is, therefore, a citizen of Delaware and New York.

16. Defendant Sanofi US Services Inc. is a corporation organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey. *Id.* ¶ 33. Sanofi US Services Inc. is, therefore, a citizen of Delaware and New Jersey.

[1] Plaintiff dismissed Defendants Boehringer Ingelheim Corporation, GlaxoSmithKline, plc, and Sanofi S.A., and thus this Court need not consider their citizenship for purposes of removal. **Exhibit A,** at 001. In any event, Boehringer Ingelheim Corporation, GlaxoSmithKline, plc, and Sanofi S.A. are foreign entities and are not citizens of California. *See* Compl. ¶¶ 26, 30, 34.

17. Defendant Sanofi-Aventis U.S. LLC is a limited liability company organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey. *Id.* ¶ 35. The sole member of Sanofi-Aventis U.S. LLC is Sanofi US Services Inc., a Delaware corporation with its principal place of business in New Jersey. Defendant Sanofi-Aventis U.S. LLC is, is therefore, a citizen of Delaware and New Jersey.

18. Defendants Does 1 through 100 are sued under "fictitious names." *Id.* ¶¶ 41-47. Therefore, their citizenship must be ignored for purposes of determining the propriety of removal. *See* 28 U.S.C. § 1441(b)(1) ("In determining whether a civil action is removable on the basis of the jurisdiction under section 1332(a) of this title, the citizenship of defendants sued under fictitious names shall be disregarded.").

19. Because Plaintiff is a citizen of California and the properly joined defendants are citizens of states other than California, complete diversity exists between Plaintiff and the properly joined defendants. *See* 28 U.S.C. §§ 1332, 1441.

II. The Retailer Defendants Are Fraudulently Joined

20. The Retailer Defendants are fraudulently joined, and their California citizenship should therefore be disregarded for purposes of removal.

21. A defendant is fraudulently joined and its presence in the lawsuit is ignored for purposes of determining diversity where there is no "possibility that a state court would find that the complaint states a cause of action" against it. *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 549 (9th Cir. 2018). *See also Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001) (a defendant is fraudulently joined "if the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to the settled rules of the state") (citing *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987)); *Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998) (same).

22. Here, the Retailer Defendants are fraudulently joined because: (1) retailers cannot unilaterally change an FDA-approved label or alter the highly regulated manufacturing processes as mere sellers of Ranitidine-Containing Drugs, and the claims against them are accordingly

preempted; and (2) Plaintiff does not plead a cognizable negligence action against the Retailer Defendants.

A. Plaintiff's Strict Liability Claims Against the Retailer Defendants Are Preempted.

23. Plaintiff's claims for strict products liability, under failure-to-warn and manufacturing-defect theories, against the Retailer Defendants are preempted by federal law. As a result, there is no "possibility that a state court would find that the complaint states a cause of action" against the retailers. *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 549 (9th Cir. 2018).

24. In *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011), the Supreme Court held that claims involving an FDA-approved product are preempted under federal law when a defendant cannot unilaterally satisfy state-law duties without FDA's prior approval. *Id.* at 623–24 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which in turn is dependent on the exercise of judgment by a federal agency, that party cannot ***independently*** satisfy those state duties for pre-emption purposes." *Id.* at 623–24 (emphasis added); *see also Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). In *Mensing*, the Supreme Court announced this preemption principle in the context of product liability actions against manufacturers of generic drugs. *Mensing*, 564 U.S. at 610. The manufacturers argued that, under federal drug regulations, they are "prevented . . . from independently changing their generic drugs' safety labels." *Id*. at 617. Consequently, they asserted, holding them liable under state law for failure to "adequately and safely label their products," would directly conflict with labeling requirements under federal law. *Id*. The Supreme Court agreed: Because generic manufacturers are unable to comply with both state and federal law, state failure-to-warn claims against generic drug manufacturers must be preempted. *Id*. at 618–620, 614 ("If the Manufacturers had independently changed their labels to satisfy their state-law duty [to attach a safer label], they would have violated federal law.").

25. The same preemption analysis that the Supreme Court articulated in *Mensing* bars claims against pharmaceutical distributors or retailers that stand even further removed than generic

manufacturers from the ability to change drug labeling that the FDA has approved. Only the party that submits the New Drug Application (the "NDA") to obtain FDA approval to market a drug can seek to change the drug's labeling after initial approval. 21 C.F.R. § 314.71(a); *id*. § 314.70(a)(4) ("The applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented . . . ."). Here, the Retailer Defendants are not, and never were, the holders of the Zantac NDA. Rather, they are named solely in their capacity as retailers that sold FDA-approved products manufactured by other parties.[2] Therefore, they had no authority to unilaterally change the product's labeling.

26. In fact, had the Retailer Defendants provided warnings about risks not included in Zantac's approved product labeling, they would have been breaking federal law, and would be subject to potential civil and/or criminal penalties for "misbranding." 21 U.S.C. §§ 333, 334. FDA regulations on misbranding prohibit any person, including a pharmaceutical distributor, from issuing any warning that is not consistent with the drug's FDA-approved labeling. 21 C.F.R. § 201.100(d)(1). Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "FDCA"), when FDA approves a drug for marketing, it also approves the drug's labeling, including information about the drug's potential risks and benefits. 21 U.S.C. § 355(d).

27. The FDCA and its implementing regulations provide that a drug is misbranded if its labeling is "false and misleading in any particular." 21 U.S.C. § 352(a); *id*. § 321(n); *id*. § 331(a), (b), (k); 21 C.F.R § 201.6(a). A statement about a drug's risks would be considered "false and misleading" if FDA has not found it to be properly substantiated. 40 Fed. Reg. 28,584 (1975) ("In short, a drug is misbranded if its labeling makes claims that have not been properly substantiated.").

[2] Plaintiff alleges that one retailer, Safeway Health, Inc., has "labeled, distributed, and marketed generic Ranitidine-Containing Drugs manufactured by Perrigo Company, plc and Dr. Reddy's Laboratories Ltd on behalf of Defendant Safeway, Inc. and labeled and marketed by Safeway Health, Inc. as 'Safeway Care' products." Compl. ¶ 38. Insofar as the Complaint could be interpreted to include a claim against Retailer Defendant Safeway as a seller of its own generic version of ranitidine under the "Safeway Care" name, Compl. ¶ 40, Safeway Health would still have no ability to alter the FDA-approved labeling for ranitidine medications whether sold under the name "Safeway Care" or any other name. *Mensing*, 564 U.S. at 617. But Plaintiff does ***not*** allege he ingested Safeway Care products. Compl. ¶ 10. Instead, Plaintiff includes Safeway Health, Inc. under the heading "Retailer Defendants" along with the other retailers, not under the heading "Manufacturer Defendants." *Id.* at p. 10. Plaintiff likewise asserts negligent product design, negligent manufacture, and negligent misrepresentation claims only against the Removing Defendants, not Safeway Health, Inc. *See id.* at Counts IV, V and VI.

By definition, an unapproved warning by a distributor or retailer that is inconsistent with the approved drug labeling would not have been found to be substantiated by FDA and, thus, would constitute misbranding.[3]

28. Applying this Supreme Court precedent, numerous federal courts have accordingly held that failure-to-warn claims asserted against pharmaceutical distributors are preempted because the distributors cannot change approved product labeling. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012) ("As a distributor of Fosamax, Watson has no power to change Fosamax labeling. That power lies with the applicant who filed the New Drug Application . . . seeking approval to market Fosamax."); *Pierik v. GE Healthcare Inc.*, No. 1:18-cv-07733, 2019 WL 4686551, at *1 (N.D. Ill. June 18, 2019) ("As McKesson is alleged to be a distributor rather than a manufacturer of Omniscan and MultiHance, I cannot draw a reasonable inference that McKesson had the ability to modify the warning labels of those drugs. Plaintiffs' claims against McKesson are preempted . . . ."); *Smith v. GE Healthcare, Inc.*, No. 3:19-cv-00492, 2019 WL 4565246 (W.D. La. Sept. 4, 2019) (finding failure-to-warn claims preempted because "McKesson has no authority to unilaterally change or add to the Omniscan labeling" as a pharmaceutical distributor); *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364–65 (N.D. Ga. 2016) ("A distributor, even of a brand name drug, has no power to change . . . labeling. That power lies with the applicant who filed the New Drug Application.") (citations and quotation marks omitted); *In re Yasmin & Yaz Prods. Liab. Litig.*, MDL No. 2100, 2014 WL 1632149, at *6 (S.D. Ill. Apr. 24, 2014) ("Under applicable federal regulations, generic distributors have no more authority than generic manufacturers to alter a drug's composition, label, or design. Accordingly, the principles announced in *Mensing* . . . are equally applicable to generic distributors."). Supreme Court precedent mandates the same result here.

[3] Plaintiff's allegation that the alleged failure to warn was not limited to the Ranitidine-Containing Drugs' labeling does not save this claim. Compl. ¶ 208. The term "labeling" under FDA regulations is broad and includes "all labels and other written, printed, or graphic matter." 21 U.S.C. § 321(m); *see also* 21 C.F.R. § 1.3 (same). Thus, all materials disseminated by pharmaceutical distributors about a drug's risks and benefits, including promotional and other materials, must be "consistent with and not contrary to . . . the approved or permitted labeling." 21 C.F.R. § 201.100(d)(1); 73 Fed. Reg. 2848, 2850 n.3 (2008) ("Federal law governs not only what information must appear in labeling, but also what information may not appear.").

29. Plaintiff's manufacturing-defect claim against the Retailer Defendants is preempted for the same reason as Plaintiff's failure-to-warn claim: under federal law, the Retailer Defendants could not have altered the manufacturing of Zantac. If the Retailer Defendants manufactured Zantac in a different manner, they would be liable under the FDCA for the introduction into interstate commerce of an unapproved and misbranded new drug. *See* 21 U.S.C. § 331(a) and (d).

30. FDA highly regulates the manufacturing of drugs and associated processes. *See* FDCA § 505; 21 U.S.C. § 355. As a result, the NDA holder must describe and disclose to FDA all manufacturers of its products. *See* 21 U.S.C. § 355(b)(1)(D) (NDA must contain "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug."); 21 C.F.R. § 314.50(d)(i) (NDA must contain "a detailed technical chemistry, manufacturing, and controls section," detailing, among other things "the name and address of the drug substance's manufacturer" as well as "the name and address of each manufacturer of the drug product; [and] a description of the manufacturing and packaging procedures and in-process controls for the drug product."). To add or change a manufacturer, the NDA holder must accordingly submit a supplement to its NDA. *See* 21 C.F.R. § 314.70(a). Just as only the NDA holder can change drug labeling, only the NDA holder has authority to submit a supplement to its NDA to add or change a manufacturer. *See* 21 C.F.R. § 314.71(a) ("Only the applicant may submit a supplement to an application."). Manufacturing a drug out of compliance with an approved NDA causes the product to be an unapproved new drug in violation of the FDCA. 21 U.S.C. § 331(d) ("The following acts are prohibited: . . . The introduction or delivery for introduction into interstate commerce of any article in violation of section . . . 505 (21 U.S.C. § 355)").

31. None of the Retailer Defendants was identified in the Zantac NDA as an authorized manufacturer of Zantac or listed and registered with FDA to manufacture Zantac. Nor did any Retailer Defendant have the authority to designate itself as a manufacturer pursuant to an approved NDA because none is an NDA holder. Had a Retailer Defendant nevertheless manufactured and sold Zantac in a different manner to avoid alleged state-law liability, that would have violated the FDCA by introducing an unapproved new drug into interstate commerce. *See* 21 U.S.C. § 331(d)

("The following acts are prohibited: . . . The introduction or delivery for introduction into interstate commerce of any article in violation of section . . . 505"). In addition, manufacturing Zantac without appropriately registering and listing with FDA would cause the resulting product to be misbranded. 21 U.S.C. § 352(o) (A drug or device shall be deemed misbranded "[i]f it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered"). Both actions would subject retailers to civil and/or criminal penalties. *See* 21 U.S.C. § 333(a); 21 U.S.C. § 303(a)(1) ("Any person who violates a provision section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both."). Thus, under the settled preemption principles articulated in *Mensing*, there is no "possibility that a state court would find that the complaint states a cause of action" against the Retailer Defendants. *Grancare, LLC*, 889 F.3d at 549 (internal quotation marks omitted).

32. Some district courts have remanded cases where removals were based on preemption of similar claims against distributors, though acknowledging the logic of the argument.[4] These cases are not binding, and the Court need not follow them. Indeed, this very issue is currently pending before the United States Court of Appeals for the Ninth Circuit. *See Geisse v. Bayer HealthCare Pharm. Inc.*, No. 17-CV-07026-JD, 2019 WL 1239854, at *2–*3 (N.D. Cal. Mar. 18, 2019), *appeal docketed*, No. 19-15783 (9th Cir. Apr. 17, 2019).

33. Nor is the reasoning of those cases persuasive. Most invoked *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1044 (9th Cir. 2009), for the proposition that it is inappropriate to examine the

[4] *See Geisse v. Bayer HealthCare Pharm. Inc.,* No. 17-CV-07026-JD, 2019 WL 1239854, at *3 (N.D. Cal. Mar. 18, 2019), *appeal docketed*, No. 19-15783 (9th Cir. Apr. 17, 2019) ("[P]reemption goes to the merits of the plaintiff's case and entails a degree of analysis that does not render a state law claim obviously barred or frivolous for fraudulent joinder purposes."); *Dodich v. Pfizer Inc.*, No. C 18-02764 WHA, 2018 WL 3584484, at *3 (N.D. Cal. July 26, 2018) ("Although logical, neither *Mensing* nor *Bartlett* specifically dealt with distributors and defendants do not identify binding authority extending the decisions. As such, it is not manifest that plaintiff has no possible claim against McKesson under California law."); *Hatherley v. Pfizer, Inc.*, No. CIV 2:13-00719 WBS, 2013 WL 3354458, at *6 (E.D. Cal. July 3, 2013) ("Thus, while the argument that distributors of brand name drugs are the same as generic manufacturers may be persuasive, unless and until this rational ***is*** extended, it is not obvious that plaintiffs have no claim against McKesson under California law because of a preemption defense.") (emphasis in original) (citations and quotation marks omitted); *In re Abilify (aripiprazole) Prods. Liab. Litig.*, 3:16-MD-2734, 2018 WL 6258903, at *5 (N.D. Fla. Nov. 8, 2018) (noting the "conceptual, and frankly, practical appeal" of the argument).

affirmative defense of preemption in the context of a motion to remand. But *Hunter* involved a common defense that would "effectively decide[] the entire case" by barring claims against ***all*** defendants. *Id.* at 1045 (internal quotation marks omitted). Not so here. Although the Removing Defendants have a variety of dispositive defenses (including some based on different federal preemption arguments), the claims against the Retailer Defendants are barred here for a different reason that does not apply to the Removing Defendants: the Retailer Defendants never had labeling or manufacturing responsibility for the product, making it impossible for them to unilaterally change the label or manufacturing of the product. *Cf. id.* at 1044.

34. In addition, no searching inquiry into the merits of the case is required to find that the claims against the Retailer Defendants are preempted. *Hunter*, 582 F.3d at 1044 (explaining that only a "summary inquiry [was] appropriate" to determine whether an in-state defendant was fraudulently joined) (citations and quotation marks omitted). Here, preemption is a legal defense that applies because of the simple and undisputed fact that the Retailer Defendants never held regulatory authority to alter the labeling or manufacture of the product. The Court need not review or determine any facts concerning the Retailer Defendants' conduct or the scientific issues involved in the litigation to assess preemption.

35. Indeed, Defendants have already successfully urged this basis for removal in the Zantac litigation. An action was filed in Florida state court against some of the instant defendants and a non-diverse retailer, Publix. As here, the plaintiff brought claims against all defendants for strict products liability, and the defendants removed the case to federal court on the basis of fraudulent joinder. Following removal, the plaintiff did not oppose defendants' removal and, instead, voluntarily dismissed Publix from the case. That case is now coordinated in the MDL. *See* Notice of Removal, *Galimidi v. Sanofi US Servs. Inc.*, No. 1:10-cv-24395-BB, ECF 1 (S.D. Fla. Oct. 23, 2019); *see also* Notice of Voluntary Dismissal Without Prejudice as to Publix Super Markets, Inc., *In re: Zantac (Ranitidine) Prods. Liab. Litig.*, No. 9:20-md-2924, ECF 259 (S.D. Fla. Mar. 6, 2020).

B. Plaintiff Fails to Plead a Cognizable Negligence Claim against the Retailer Defendants under California Law.

36. There is no possibility that Plaintiff could prevail on his negligence claim against the Retailer Defendants under California law because a seller of a product does not have a duty to investigate or test products stocked on its shelves for unforeseen risks.

37. The Complaint asserts that in January 2020, an FDA-certified pharmaceutical testing laboratory called Emery Pharma conducted tests revealing that NDMA accumulates in Ranitidine-Containing Drugs exposed to elevated temperatures. *See* Compl. ¶ 148. It further alleges that subsequent FDA testing revealed that NDMA levels could increase even under normal storage conditions. Compl. ¶ 150.

38. The thrust of the Complaint is that the Retailer Defendants were negligent for not themselves earlier investigating and testing Ranitidine-Containing Drugs to uncover these alleged facts, and accordingly for storing the product in conditions that allegedly led to NDMA formation. *See, e.g.*, Compl. ¶ 291 ("Defendants acted below the standard of care by storing and dispensing Ranitidine-Containing Drugs to Plaintiff without first undertaking efforts to ensure that the drugs were safe for human use by, for example, consulting the available medical literature evidencing the potential human health dangers associated with the storage of Ranitidine-Containing Drugs and the formation of NDMA within Ranitidine-Containing Drugs when the drugs are stored at particular temperatures.").

39. Plaintiff's claim that the Retailer Defendants should have determined that Ranitidine-Containing Drugs degrade and form NDMA when stored at particular temperatures or lengths of time seeks to impose a duty to investigate and test that California law does not recognize. California law is clear that "a dealer who purchases and sells an article in common and general use, in the usual course of trade, without knowledge of its dangerous qualities ***is not under duty*** to exercise ordinary care to discover whether it is dangerous or not." *See Sears, Roebuck & Co. v. Marhenke*, 121 F.2d 598, 600 (9th Cir. 1941) (applying California law) (emphasis added and citations omitted); *see also Tourte v. Horton Mfg. Co.*, 108 Cal. App. 22, 24 (1930) (affirming the holding of the Superior Court of Alameda County that the seller of a washing machine had no duty to examine the product where

there was a latent defect unknown to the seller). *Cf. Burgess v. Montgomery Ward & Co.*, 264 F.2d 495, 497 (10th Cir. 1959) (holding that it would be "completely unreasonable to expect the shopkeeper to perform the inspection or test which would have revealed to an expert the defect in the ladder rail"); *Ziglar v. E. I. Du Pont De Nemours & Co.*, 152, 280 S.E.2d 510, 514 (N.C. App. 1981) (holding that retailer of inherently dangerous toxic substance was under no duty to detect or remedy hidden defect); *Odum v. Gulf Tire & Supply Co.*, 196 F. Supp. 35, 36 (N.D. Fla. 1961) (holding that "a retailer or wholesaler is not under a duty to inspect manufactured articles of a complex nature for defects which are latent"); *Meyer v. Rich's Inc.*, 12 S.E.2d 123, 123 (Ga. App. 1940) (a seller of men's suits had no duty to analyze the suit chemically and was therefore not liable for buyer's injuries caused by poisonous dye and chemicals in suit).[5]

40. In *Sears*, for example, after suffering burns from hot water leaking from a rubber hot water bag, plaintiff sued the retailer from whom he purchased the product. 121 F.2d at 599. An expert testified that the defect in the bag was in the faulty method of construction of the stopper and the socket so that there was a slight leakage of water around the stopper. *Id.* The Ninth Circuit explained that the question of whether or not the retailer "should have known of such defects depends upon whether or not the vendor who sells goods manufactured by another is obligated to inspect the goods to determine whether or not they are defective." *Id.* at 600. It squarely held that the retailer had no such duty. *See id.* Thus, the retailer was under no obligation to inspect the product whether the defects "could only be discovered by such investigations as were made by the experts, or could have been ascertained by the simple test of filling the bag with water and inverting it after the stopper had been screwed into its socket." *Id.*

41. Plaintiff's claim here seeks to impose an even more obviously untenable duty than in *Sears.* The alleged defect in the hot water bottle in *Sears* could have been discovered by a "simple test." 121 F.2d at 600. Yet here, Plaintiff's theory would impose upon every California retailer

[5] Plaintiff's conclusory and unsupported allegation that the Retailer Defendants failed to follow their own "established practices and procedures" to store the products presupposes that the Retailers owed a duty to investigate and test the products to learn that they could potentially form NDMA through certain storage conditions. Only if they had conducted such testing and investigation could formation of NDMA be a foreseeable risk of deviating from established storage practices.

who sells over-the-counter medications (which, by federal regulation 21 CFR § 211.132, they receive in sealed tamper-resistant packaging) the obligation to conduct their own independent, specialized testing to determine the safety of every lot of every over-the-counter medication stocked on its shelves.

42. This would be a wholly unprecedented undertaking to require of every retailer in California at pains of negligence liability. Stability testing of pharmaceutical products involves a complex set of procedures that require considerable cost, time, and scientific expertise. Under federal regulations, for instance, a manufacturer must submit a written protocol that includes, *inter alia*, sample size and test intervals based on statistical criteria for each attribute examined; storage conditions for samples retained for testing; specific test models; testing of the drug product in the same container-closure system as that in which the drug product is marketed; and testing of the drug product at the time of dispensing as directed in the labeling. 21 C.F.R. § 211.166(a)(1)-(5). Such testing must include an adequate number of batches at various storage conditions as defined in the protocol. 21 C.F.R. § 211.166(b). Pharmaceutical companies often contract with a Contract Manufacturing Organization ("CMO") to conduct the stability testing. Such testing can cost anywhere from $40,000-$60,000 per product. *See* PCI Synthesis, How to Know When to Toss Your Prescription Drug or Refrigerate It (June 28, 2017), *available at* https://www.pcisynthesis.com/how-to-know-when-to-toss-your-prescription-drug-or-refrigerate-it/.

43. Yet under Plaintiff's theory, not just the specific Retailer Defendants here but "mom and pop" grocery or convenience stores throughout the State would be required to conduct such detailed scientific investigations of the pharmaceutical products they sell to guarantee their safety. Nor would Plaintiff's novel theory be limited to storage conditions for pharmaceuticals; retailers would have to conduct extensive testing of ***all*** of their products to discover any latent dangers and warn against them. *See, e.g.*, *Burgess v. Montgomery Ward & Co.*, 264 F.2d 495, 497 (10th Cir. 1959) ("Montgomery Ward is operating a retail store, not a testing laboratory. If Montgomery Ward were obliged to test this [allegedly defective] ladder for structural strength, so is the operator of every retail store in the villages which dot the Kansas prairies."). This is not the "ordinary care"

that the law demands of retailers who sell over-the-counter pharmaceuticals, or any other common product for that matter.

44. The Complaint therefore states no cognizable claim against the Retailer Defendants under California negligence law. The Retailer Defendants are, therefore, fraudulently joined and their California citizenship should be disregarded for purposes of removal.

III. The Amount-in-Controversy Requirement Is Satisfied

45. Plaintiff's claims also satisfy the amount in controversy requirement set forth in 28 U.S.C. § 1332(a).

46. "[A] defendant's notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold." *Dart Cherokee Basin Operating Co., LLC v. Owens*, 135 S. Ct. 547, 554 (2014). "[T]he defendant's amount-in-controversy allegation should be accepted when not contested by the plaintiff or questioned by the court," and "[e]vidence establishing the amount is required by § 1446(c)(2)(B) only when the plaintiff contests, or the court questions, the defendant's allegation." *Id.* at 553–54.

47. Plaintiff seeks several categories of damages, including compensatory damages, exemplary damages, and punitive damages. *See* Compl., Prayer for Relief ¶ 295(a)-(b).

48. The Complaint includes seven causes of action, and alleges that Plaintiff's use of Zantac caused Plaintiff to suffer "significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae." *Id.* ¶ 14. It further asserts that Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage" caused by Zantac. *Id.*

49. Recently, in denying remand, a court of this Circuit found that the amount in controversy was met in a Zantac-related case similarly alleging a cancer injury and seeking compensatory and punitive damages. There, the Court held that even applying a "conservative estimate" the allegations "on their face" established that the amount in controversy was met. Order, *Brooks v. Sanofi*, No. 2:20-cv-565, ECF 13, at 6-7 (D. Nev. Apr. 13, 2018).

50. Courts have similarly found that allegations of serious injury in products liability actions, such as those Plaintiff makes here, support an inference that the amount-in-controversy requirement has been met. *See Mullaney v. Endogastric Sols. Inc.*, No. 11-62056-CIV, 2011 WL 4975904, at *2 (S.D. Fla. Oct. 19, 2011) (inferring that amount in controversy requirement was met where plaintiff alleged that he underwent "surgical intervention that required additional life saving medical treatment" and suffered "serious, permanent and disabling injuries"); *see also Geographic Expeditions, Inc. v. Estate of Lhotka*, 599 F.3d 1102, 1107–08 (9th Cir. 2010) ("even though the state court complaint does not specify an amount" it satisfied amount in controversy requirement by requesting damages for, among other things, wrongful death, loss of consortium, and negligence, as well as funeral, medical and burial expenses); *Campbell v. Bridgestone/Firestone, Inc.*, No. CIVF051499-FVSDLB, 2006 WL 707291, at *2 (E.D. Cal. Mar. 17, 2006) (apparent from complaint that amount in controversy met where plaintiffs asserted strict products liability, negligence, and breach of warranty claims against multiple defendants and sought compensatory damages, hospital and medical expenses, general damages, and loss of earning capacity).

51. Based on Plaintiff's allegations, the amount in controversy exceeds $75,000, exclusive of interest and costs.

IV. Procedural Requirements of Removal Are Satisfied

52. This Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b). The Removing Defendants have received a copy of, but have not yet been served with, the Complaint.

53. The Northern District of California is the federal judicial district encompassing the Superior Court of the State of California in and for Alameda County, where this suit was originally filed. Venue is therefore proper in this district under 28 U.S.C. §§ 84(a) and 1441(a).

54. **Intradistrict Assignment.** Pursuant to Civil Local Rule 3-2(c) and (d), this action should be assigned to the Oakland or San Francisco Division, because the action arose in Alameda County.

55. Removal pursuant to 28 U.S.C. § 1441(a) requires that "all defendants who have been properly joined and served must join in or consent to the removal of the action." 28 U.S.C. § 1446(b)(2)(A).

56. All of the Removing Defendants join in and consent to this removal.

57. No other Defendant is required to consent to this removal. On information and belief, as of the time of filing this Notice, the Retailer Defendants have not been served with the Complaint. Therefore, the Retailer Defendants are not required to join in or consent to the removal of this action. *See Destfino v. Reiswig*, 630 F.3d 952, 957 (9th Cir. 2011) (finding an exception to the consent rules where a defendant had not been properly served at the time of removal). Moreover, the Retailer Defendants are fraudulently joined and therefore are not required to join in the removal. *See United Computer Sys. Inc. v. AT&T Corp.*, 298 F.3d 756, 762 (9th Cir. 2002). The unidentified defendants Does 1-100 are not required to consent to removal. *See Hafiz v. Greenpoint Mortg. Funding*, 409 F. App'x 70, 72 (9th Cir. 2010) (nominal parties are not required to consent to removal).

58. The Removing Defendants are providing Plaintiff with written notice of the filing of this Notice of Removal as required by 28 U.S.C. § 1446(d).

59. Pursuant to 28 U.S.C. § 1446(d), the Removing Defendants are filing a copy of this Notice of Removal with the Clerk of the Superior Court of the State of California in and for Alameda County.

60. Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings, orders and other papers filed in the state court action—as available from the state court docket or otherwise made available to the Removing Defendants at the time of filing this Notice—are attached hereto as **Exhibit A**.

61. If any question arises regarding the propriety of the removal of this action, the Removing Defendants respectfully request the opportunity to present a brief and be heard at oral argument in support of removal.

62. No previous application has been made for the relief requested herein.

63. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action in which the amount in controversy exceeds $75,000, exclusive of interest and costs, and is an action between citizens of different states.

V. Demand for Jury Trial

64. The Removing Defendants hereby demand a separate jury trial on all claims and issues so triable.

WHEREFORE, the Removing Defendants give notice that the matter bearing Case No. RG20061576 pending in the Superior Court of the State of California in and for Alameda County is removed to the United States District Court for the Northern District of California, and requests that this Court retain jurisdiction for all further proceedings in this matter.

Dated: June 15, 2020

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